

1 **METHODS AND APPARATUS FOR TREATMENT OF EYE DISORDERS**
2 **USING ARTICULATED-ARM-COUPLED ULTRAVIOLET LASERS**

4 J. T. Lin (filed on 8/21/03)

6 **BACKGROUND OF THE INVENTION**

8 1. Field of the Invention

9 The present invention relates to methods and apparatus for the treatment of
10 presbyopia and glaucoma using articulated-arm-coupled ultraviolet laser to
11 ablate the sclera tissue.

13 2. Prior Art

15 Corneal reshaping including a procedure called photorefractive
16 keratectomy (PRK) and a new procedure called laser assisted in situ
17 keratomileusis, or laser intrastroma keratomileusis (LASIK) have been
18 performed by lasers in the ultraviolet (UV) wavelength of (193 - 213) nm. The
19 commercial UV refractive lasers include ArF excimer laser (at 193 nm) and
20 other non-excimer, solid-state lasers such as those proposed by the present
21 inventor in 1992 (US pat. no. 5,144,630) and in 1996 (US pat. No. 5,520,679).
22 The above-described prior arts using lasers to reshape the corneal surface
23 curvature, however, are limited to the corrections of myopia, hyperopia and
24 astigmatism.

25 Refractive surgery using a scanning device and lasers in the mid-
26 infrared (mid-IR) wavelength was first proposed by the present inventor in US
27 Pat. No. 5,144,630 and 5,520,679 and later proposed by Telfair et. al., in US
28 Pat. No. 5,782,822, where the generation of mid-IR wavelength of (2.5-3.2)
29 microns were disclosed by various methods including: the Er:YAG laser (at 2.94
30 microns), the Raman-shifted solid state lasers (at 2.7-3.2 microns) and the
31 optical parametric oscillation (OPO) lasers (at 2.7-3.2 microns).^a

32 Corneal reshaping may also be performed by laser thermal coagulation
33 currently conducted by a Ho:YAG laser (at about 2 microns in wavelength)
34 proposed by Sand in US Pat. 5,484,432. This method, however, was limited to

1 low-diopter hyperopic corrections. Strictly speaking this prior art did not
2 correction the true "presbyopia" and only performed the mono-vision for
3 hyperopic patients. A thermal laser is required and the laser treated area was
4 within the optical zone diameters of about 7 mm.

5 Ruiz in US pat. No. 5,533,997 proposed the use of laser ablation of
6 cornea surface to correct presbyopic patients. This prior art, however, must
7 generate multifocal (or bifocal) surface on the central portion of the cornea in
8 order to achieve the desired presbyopia correction. Corneal curvature change
9 by laser ablation in this prior art, however, did not actually resolve the intrinsic
10 problems of presbyopic patient caused by age where the cornea lens loss its
11 accommodation as a result of loss of elasticity due to age.

12 All the above-described prior arts are using methods to change the
13 cornea surface curvature either by tissue ablation (such as in UV laser) or by
14 thermal shrinkage (such as in Ho:YAG laser) and all are using lasers onto the
15 central portion of the cornea.

16 The alternative method for presbyopia correction, therefore, is to
17 increase the accommodation of the presbyopic patients by change the intrinsic
18 properties of the sclera and ciliary tissue to increase the lens accommodation
19 without changing the cornea curvature. This method of sclera ablation is
20 fundamentally different from all the prior arts including that of Ruiz, in which
21 reshaping cornea curvature into multifocal shape was required for presbyopia
22 correction.

23 To treat presbyopic patients, or the reversal of presbyopia, using the
24 concept of expanding the sclera by mechanical devices has been proposed by
25 Schachar in U.S. patents 5,489,299, 5,722,952, 5,465,737 and 5,354,331.
26 These mechanical approaches have the drawbacks of complexity and are time
27 consuming, costly and have potential side effects. To treat presbyopia, the
28 Schachar patents Nos. 5,529,076 and 5,722,952 propose the use of heat or
29 radiation on the corneal epithelium to arrest the growth of the crystalline lens
30 and also propose the use of lasers to ablate portions of the thickness of the
31 sclera. However, these prior arts do not present any details or practical methods
32 or laser parameters for the presbyopic corrections. No clinical studies have
33 been practiced to show the effectiveness of the proposed concepts. The
34 concepts proposed in the Schachar patents, 5,354,331 and 5,489,299,
35 regarding lasers suitable for ablating the sclera tissues were incorrect because
36 he did not identify which lasers are "cold lasers". Many of his proposed lasers

1 are thermal lasers which will cause thermal burning of the cornea, rather than
2 tissue ablation. Furthermore, the clinical issues, such as locations, patterns and
3 depth of the sclera tissue removal were not indicated in these prior patents. In
4 addition, it is essential to use a scanning or fiber-coupled laser to achieve the
5 desired ablation pattern and to control the ablation depth on the sclera tissue.
6 Schachar's methods also require the weakening of the sclera and increase its
7 diameter by expansion, whereas the proposed concept of the present invention
8 provides new mechanisms for accommodation.

9 The "presbyopia" correction proposed by Ruitz (US Pat. No. 5,533,997)
10 using an excimer (ArF) laser also required the corneal surface to be reshaped
11 to form "multifocal" effort for a presbyopia patents to see near and far. However,
12 Ruitz's "presbyopia" correction is fundamentally different from that of the
13 present patent which does not change the corneal curvature. The presbyopia
14 correction proposed in the present patent is to increase patient's
15 accommodation rather than reshaping the cornea into "multifocal" surface.

16 The technique used in the prior art of Bille (Pat. No. 4,907,586) required
17 a quasi- continuous laser having pulse duration less than 10 picoseconds and
18 focused spot less than 10 micron diameter and the laser is confined to the
19 interior of a selected tissue to correct myopia, hyperopia or astigmatism. Bille
20 also proposed the laser to focus into the lens of an eye to prevent presbyopia.
21 This prior art system is very complicate and needs a precise control of the laser
22 beam size and focusing position. Furthermore, clinical risk of cataract may
23 occur when laser is applied into the lens area.

24 Another prior art proposed by Spencer Thornton (Chapter 4, "Surgery
25 for hyperopia and presbyopia", edited by Neal Sher (Williams & Wilkins, MD,
26 1997) is to use a diamond knife to incise radial cuts around the limbus areas. It
27 requires a deep (90%-98%) cut of the sclera tissue in order to obtain
28 accommodation of the lens. This method, however, involves a lot of bleeding
29 and is difficult to control the depth of the cut which requires extensive surgeon's
30 skill. Another drawback for presbyopia correction provided by the above-
31 described incision methods is the major post-operative regression of about
32 (30%-80%). And this regression is minimum in the laser-ablation method
33 proposed in the present invention. We note that there is intrinsic difference
34 between the ablation-method proposed in this invention and the knife-incision.
35 The sclera space produced by the incision method is not permanent and may
36 be greatly reduced during the tissue healing and cause the regression. This

1 major source of regression in incision method however will not occur in the laser
2 or non-laser ablation-methods as proposed in this invention, where portion of
3 the sclera tissue is permanently removed.

4 One of the important concepts proposed in the present invention is to
5 support the post-operative results which show minimum regression. We
6 proposed that the laser ablated sclera tissue "gap" will be filled in by the sub-
7 conjunctival tissue within few days after the surgery. This filled in sub-
8 conjunctival tissue is much more flexible than the original sclera tissue.
9 Therefore the filled-in gap in the sclera area will cause the under laying ciliary
10 body to have more space to move. This in turn will allow the ciliary body to
11 contract or expand the zonular fiber which is connected to the lens, when the
12 presbyopic patient is adjusting his lens curvature to see near and far. The above
13 described sub-conjunctival tissue filling effects and the increase of "flexibility" of
14 the sclera area are fundamentally different from the scleral "expansion"(or
15 weakening) concept proposed by the prior arts of Schachar and proposed by
16 the implant of a scleral band. In the present invention, the laser ablated sclera
17 area is not weakening, it becomes more flexible instead.

18 The prior art by the present inventor, US Pat. No. 6,263,879 was limited
19 to scanning device which has drawback of de-centration caused by eye
20 movement, and it is hard to control the ablation depth due to the fact that the
21 scanning laser beam is not perpendicular to the scleral surface. Another prior
22 art of Lin, US Pat. No. 6,258,082 proposed the fiber-coupled lasers which
23 however was mainly designed for an IR-laser because the coupling efficiency of
24 existing fibers was very poor, less than 30% when laser wavelength shorter than
25 0.27 microns.

26 In addition, the fiber-coupled laser has drawbacks of high fiber cost and
27 the fiber is easy to break, in which the fiber tip was contacted to the scleral
28 which caused tissue to stick to the tip and cleaning is required during the
29 surgery. No high UV-transparent fibers are currently available for the application
30 of high peak-power UV lasers, particularly for the spectral range of (0.19 – 0.3)
31 microns, operated in the nanosecond pulse duration.

32 Articulated arms have been commercially used to deliver laser beams.
33 However, they are mainly used for dermatological uses and are limited to
34 spectrum of visible (500-700) nm and IR (1-3) microns. No UV lasers of (190-
35 300) nm have been developed and coupled to articulated arm for the treatment
36 of eye disorders including presbyopia and glaucoma. Furthermore, the

1 articulated arm for prior art uses did not require a good beam alignment or
2 centration, because of a rather large beam spot (4-15) mm, are normally used.
3 On the contrary, the presently proposed UV laser, articulated-arm system
4 requires centration/alignment better than 0.2 mm because of its much smaller
5 beam spot of (0.2-1.0) mm needed in the present invention. The dermatological
6 lasers are using the laser thermal effects to change the skin conditions,
7 whereas the present invention requires a "cold" laser for tissue ablation and
8 thermal effects must be minimized.

9 One objective of the present invention is to provide an apparatus and
10 method to obviate these drawbacks in the prior arts.

11 It is yet another objective of the present invention to use an articulated-
12 arm-coupled lasers such that the degree of vision accommodation can be
13 controlled by the ablation patterns, location, size and shapes of the removed
14 sclera tissue.

15 It is yet another objective of the present invention to define the non-
16 thermal lasers for efficient tissue ablation to present refractive power change of
17 the cornea caused by thermal effects.

18 It is yet another objective of the present invention to define the optimal
19 laser parameters and the ablation patterns for best clinical outcome for
20 presbyopia patients, where sclera ablation will increase the accommodation of
21 the ciliary muscle by the increase of the flexibility in the laser-ablated areas.

22 It is yet another objective of the present invention to provide the
23 appropriate ablation patterns which will cause effective ciliary body contraction
24 and expansion on the zonules and the lens.

25 It is yet another objective of the present invention to provide a new
26 mechanism which supports the clinical results of presbyopia correction with
27 minimum regression. One important concept proposed in the present invention
28 is to support the post-operative results which show minimum regression when
29 presbyopia is corrected by a laser ablation for the sclera tissue.

30 We proposed that the laser ablated sclera tissue "gap" will be filled in by
31 the sub-conjunctival tissue within few days after the surgery. This filled in sub-
32 conjunctival tissue is much more flexible than the original sclera tissue.
33 Therefore the filled-in gap in the sclera area will cause the underlying ciliary
34 body becomes more flexible. This will allow the ciliary body to contract or
35 expand the zonular fiber connected to the lens when the presbyopic patient is
36 adjusting his lens curvature to see near and far.

1 Another important concept proposed in the present invention is to
2 support the post-operative results which show minimum regression. We
3 proposed that the laser ablated sclera tissue "gap" will be filled in by the sub-
4 conjunctival tissue within few days after the surgery. This filled in sub-
5 conjunctival tissue is much more flexible than the original sclera tissue.
6 Therefore the filled-in gap in the sclera area will cause the underneath ciliary
7 body to contract or expand the zonular fiber connected to the lens when the
8 presbyopic patient is adjusting his lens curvature to see near and far.

9 It is yet another objective of the present invention to provide a 2-
10 component model to count for the total accommodation amplitude for treated
11 presbyopia patients.

12 It is yet another objective of the present invention to provide an
13 articulated-arm device to achieve the coupling efficiency required in sclera
14 ablation.

15 The present invention described in great detail for the treatment of
16 presbyopia may be extended to other eye disorders including glaucoma. For the
17 case of glaucoma, the laser may be used to remove sclera tissue in the area
18 where Schlemm's channel is located followed by a removal of a small portion of
19 the iris underlying this area.

20 The invention having now been fully described, it should be understood
21 that it may be embodied in other specific forms or variations without departing
22 from the spirit or essential characteristics of the present invention. Accordingly,
23 the embodiments described herein are to be considered to be illustrative and
24 not restrictive.

25 26 SUMMARY OF THE INVENTION

27
28 The preferred embodiments of the basic surgical lasers of the present
29 invention shall include ultraviolet (UV) lasers having wavelength range of about
30 (190 – 360) nm, such as ArF (at 193 nm) and XeCl (at 308 nm) excimer lasers,
31 nitrogen laser (at 337 nm) flash-lamp-pumped and diode-pumped solid state
32 lasers having wavelength range of about (190-355) nm such as Nd-YAF,
33 Er:YAG, Nd:YAG, Er:glass and Ti:sapphire laser using harmonic generation from
34 nonlinear crystals of KTP, BBO, LBO, KDP and other UV transparent crystals.
35

1 It is yet another preferred embodiment is to couple the basic lasers by
2 an articulated-arm to deliver the laser beam to treated area of the eye, in which
3 the end of the arm is connected to a short tip-tube which may be disconnected
4 for reuse after sterilization.

5 It is yet another preferred embodiment to use a 2-component model to
6 estimate the post-operation accommodation improvement which is given by
7 lens relaxation and anterior shift.

8 It is yet another preferred embodiment to focus the laser beams into a
9 desired spot size on the treated area of the eye. Various ablation patterns may
10 be generated manually via the hand piece including multiple rings of spots,
11 radial line or non-specific shapes outside the limbus.

12 It is yet another preferred embodiment to control laser beam spot size
13 by position and focal length of focusing lens and the length of the attached end
14 pieces.

15 It is yet another preferred embodiment is to ablate by the basic UV
16 lasers, a portion of the sclera tissue to increase the flexibility and available
17 space of the sclera-ciliary-zonus complex to increase the lens accommodation
18 (for presbyopia) and reduce the intraocular pressure (IOP) of the eye (for
19 glaucoma treatment).

20 It is yet another preferred embodiment to open the conjunctiva layer
21 prior to the laser ablation of the under-layer of the sclera tissue for a better
22 control of the ablation depth and for safety reasons.

23 It is yet another preferred embodiment is that the conjunctiva layer may
24 also be ablated by the UV laser without open it as a flap in order to speed up the
25 surgical procedure.

26 Further preferred embodiments of the present invention will become
27 apparent from the description of the invention which follows.

28
29
30 DETAILED DESCRIPTION OF THE INVENTION AND THE
31 PREFERRED EMBODIMENTS

32
33 A surgical laser system in accordance with the present invention
34 comprises a basic laser having wavelength in the UV spectrum is focused and
35 coupled to an articulated-arm (ATA) which is commercially available except the
36 use of UV 45 degree high reflecting coated mirrors which are mounted to each

1 of the joints. These mounts are independently adjustable for fine-tuning of laser
2 alignment and centration. The preferred ATA is attached to an end piece which
3 is used to contact the treated eye surface such that laser beam spot size and its
4 location are well defined. Using high reflecting UV mirrors, we are able to
5 achieve an overall coupling efficiency over 75% when an articulated-arm having
6 4 joints is used. This efficiency is much higher than that of a fiber is used, less
7 than 30% for spectrum range of (195-280) nm.

8 The proposed UV laser provides a "clean" cut with almost no thermal
9 tissue damage, whereas prior art using an IR laser (LIN, US Apt. 6,258,082) at
10 about 2.9 microns suffers certain degree of thermal damage, particularly around
11 the laser spot edge which has less power. It is critical that thermal effects on the
12 cornea must be minimized, otherwise patient's far vision will become "hyperopic
13 shift" caused by the thermal shrinkage of the cornea. This drawback of prior art
14 IR laser is totally eliminated when the proposed UV laser is used. Prior arts
15 using a fiber and a fiber tip to deliver the laser energy also suffers fiber-tip
16 damage when laser heating is accumulated at the tip end, unless it is efficiently
17 transported to the treated tissue. IR fiber is also easy to break and its tip end
18 can be easily stuck with sclera tissue and cause available laser power to drop
19 significantly. All these prior art drawbacks are obviated in the proposed UV laser
20 system coupled to an articulated arm which also has a much higher coupling
21 efficiency than that of an IR laser.

22 The preferred articulated arm shall have a length about (0.5-1.2) meter,
23 a minimum of 2 joints (for free rotation in x, y and z directions), connected to an
24 end piece with length about (5-20) mm. In addition, at least 2 highly UV
25 reflecting mirrors are 45 degree mounted at the joint position to reflect the laser
26 beam along the arm tube with a centration better than 0.2mm. The preferred
27 laser spot diameter is about (0.2-1.0) mm with UV energy per pulse of about
28 (0.5-10)mJ on the sclera surface, or at the output end of the articulated arm. It
29 is also a preferred requirement that the laser output alignment from the arm
30 should not deviate more than 0.2mm while keeping its power level over 85% of
31 the perfectly centered position, when the arm is freely rotated in 3 dimension.

32 According to the present invention, the preferred embodiments of the
33 basic surgical lasers for presbyopia correction and/or glaucoma procedures
34 shall include: (a) ultraviolet (UV) lasers having wavelength range of about (190 –
35 360) nm, such as ArF (at 193 nm) and XeCl (at 308 nm) excimer lasers,
36 nitrogen laser (at 337 nm) and (b) solid-state lasers using harmonic generation

1 from solid-state lasers of Nd:YAG, Nd:YLF and Alexandrite lasers where
2 nonlinear crystals of KTP, BBO or KDP may be used to up convert the
3 fundamental frequency to the desired UV range. These solid-state lasers may
4 be flash lamp pumped or diode laser pumped.

5 According to one aspect of the present invention, the preferable UV
6 laser energy per pulse on scleral surface is about (0.5-10) mJ. Focused spot
7 size of about (0.1-1.0) mm in diameter on the scleral plane is achieved by
8 means of focusing which consists of at least one spherical lens with focal length
9 of (5-100) cm. The other preferred laser parameter of this invention is the laser
10 repetition rate range of about (5-100) Hz which will provide reasonable surgical
11 speed and minimum thermal effects. The focused beam delivered to the
12 articulated arm may be scanned over the scleral surface to ablate various
13 patterns by surgeon's control of the hand piece.

14 Another preferred embodiment is to use a cylinder focusing lens to
15 generate slit shape size of (0.1-0.5) x (3-5) mm.

16 The preferred patterns of this invention include a ring-spot having at
17 least one ring with at least 3 spots in each ring, a radial-pattern having at least 3
18 radials or non-specific shapes as far as it is in a symmetric form. The preferred
19 area of the ablation is defined within two circles having diameters about 10 mm
20 and 14 mm posterior to the limbus along the radial direction of the cornea. We
21 should note that for the case of a circular laser spot, a radial ablation pattern on
22 the scleral surface may be generated either by manually scan the end tip by a
23 surgeon who hold the hand piece. For the situation of the slit spot, the surgeon
24 may easily generate the radial patterns without moving the end tip of the
25 articulated arm.

26 The preferred ablation depth of the sclera tissue is about (400-700)
27 microns with each of the radial length of about (2.5 - 5.0) mm adjustable
28 according to the optimal clinical outcomes including minimum regression and
29 maximum accommodation for the presbyopic patients. The preferred radial
30 ablation shall start at a distance about (4.0 - 5.5) mm from the corneal center
31 and extended about (2.0-5.0) mm outside the limbus. The preferred
32 embodiments of the radial patterns on the sclera area include at least 3 radial
33 lines, curved lines, ring-dots or any non-specific shapes as far as they are
34 symmetric to the center of the eye. The symmetric form is required to achieve
35 an even "force" acting on the zonous fiber for lens relaxation. Any other non-

1 specific patterns including curved lines, z-shape, t-shape lines around the area
2 outside the limbus should be within the scope of this patent.

3 It is yet another preferred embodiment is to control the laser spot on the
4 sclera surface by positioning of the focusing lens at about one focal length away
5 from the output end of the articulated arm. This focal lens is preferred to be
6 integrated inside the last section (last joint) of the arm having a typical length
7 about (5-20) cm. For safety issue, the preferred laser beam is focused (0.5-1.5)
8 cm above the sclera surface such that the beam is divergent when delivered to
9 the sclera surface. When surgeon's hand piece is held away from the eye
10 surface, the laser beam spot is always divergent and expanding to a low power
11 level. High power ablating spot is available only when end-top of the articulated
12 arm is contacted to the eye surface.

13 It is yet another preferred embodiment is to ablate a portion of the
14 sclera tissue for the treatment of eye disorders including prebyopia, (by
15 increasing accommodation) and glaucoma (by reducing the intraocular
16 pressure). In each procedure, the sclera-ciliary complex becomes more flexible
17 with increasing space between the ciliary ring and the lens. For quantitative
18 discussion, we propose the following. Let AA stands for the accommodation
19 amplitude (AA) increase after the surgery, and then the total amount of AA is
20 given by both lens relaxation (LR) and lens anterior shift (LAS) as follows:

$$21 \quad AA = -m(dS) + M(dT)$$

22 Where dS and dT stand for the amount of anterior shift and lens thickness
23 increase due to its curvature changes (curvature radius R1 and R2 decrease)
24 when the zonulus relaxes. M and m are the slopes for the AA versus LR and LAS.
25 Our calculations show that $m = (1.0-1.7)/D/\text{mm}$ depending on the initial lens
26 curvatures. The slope for LR effect is given by $M = 435/WS$, where WS is the
27 square of the lens optical zone diameter (W). For $W = (4.0-5.5) \text{ mm}$, we obtain
28 $M = (14.4-27.2) (D/\text{mm})$ which is about (15-27) times of m.

29 There are several important implications may be addressed based on
30 this new model: (1) the total accommodation AA is the sum of 2 components m
31 (due to LAS) and M (due to LR); however, the effect from M is much higher than
32 that of m; (2) for aged eyes with deformable lens capsule presbyopia may be
33 treated mainly by the LR component; (3) AS component will be the only
34 mechanism for the increase of AA when the lens capsule is extremely rigid
35 caused by age.

1 The mechanism of accommodation proposed by Schachar (US pat.
2 5,354,331 and 5,489,299) was based on the increase of ciliary ring diameter for
3 lens relaxation. These prior arts are in conflict with recently reported data based
4 on MRI imaging measurements. In addition, the second component of LAS for
5 accommodation has never been proposed in any of prior arts. During
6 accommodation, the ciliary body, based on the present new theory, is actually
7 contracted inward to the lens (or ciliary ring diameter decreases) and also
8 forward to the anterior chamber (or its depth decreases), noting that dS is
9 negative and dT is positive and AA is the sum of both components for
10 accommodation. Without using this proposed new mechanism, sclera ablation
11 would not be able to treat patients with rigid lens capsule. This new mechanism
12 is also able to explain the clinical results in our old, patients, say, age over 60.

13 While the invention has been shown and described with reference to
14 the preferred embodiments thereof, it will be understood by those skilled in the
15 art that the foregoing and other changes and variations in form and detail may
16 be made therein without departing from the spirit, scope and teaching of the
17 invention. Accordingly, threshold and apparatus, the ophthalmic applications
18 herein disclosed are to be considered merely as illustrative and the invention is
19 to be limited only as set forth in the claims.

20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36